UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,476	03/11/2004	Thomas L. Cantor	532212000100	8385

25225 7590 04/17/2007
MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
DEBERRY, REGINA M	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,476	CANTOR, THOMAS L.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *12,15,16 and 24-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,14 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

Applicant's election without traverse of Group I (claims 1-11, 13, 14, 17-23) in the reply filed on 30 January 2007 is acknowledged. Claims 12, 15, 16, 24-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 30 January 2007.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 09 July 2004 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Sequence Rules

The specification is not in compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations. When the description of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier (SEQ ID NO:), in the text and claims of the patent application. 37 CFR 1.821(a) presents a definition for nucleotide and/or amino acid sequences. This definition sets forth limits in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through

1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Please see MPEP section 2422.01.

The specification refers to sequences on page 26, paragraphs 0122-0123 and page 27, paragraphs 0128-0130, but does not identify the sequences by their sequence identifiers. The entire specification must be examined for proper sequence identifiers. Sequences appearing in drawings should be referenced in the corresponding Brief Description thereof. See 37 C.F.R. §1.58(a) and §1.83. Appropriate correction is required.

Applicant must submit a response to this Office Action and compliance with the sequence rules within the statutory period set for response to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 10, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Motte et al. (The Journal of Immunology, Vol. 138, 3332-3338, No. 10, May 1987).

Motte et al. teach monoclonal antibodies (Mab), which distinguish synthetic peptides that differ in one chemical group. Motte et al. teach a method of immunizing mice with different peptide fragments of human calcitonin (hCT and PQN-34) and human calcitonin gene related peptide (hCGRP) (page 3333, 2nd paragraph and Figure 1). Mab were purified form ascite fluids by ammonium sulfate precipitation and protein A chromatography. Enzyme-linked immunosorbent assay (ELISA) was used for hybridoma supernatant screening and determination of Mab specificity. Wells were coated with the peptides and blocked in BSA. After washing, culture supernatants, ascite fluids or purified antibody were added to the wells. Peroxidase-conjugated anti-mouse Ig rabbit antiserum was added. Enzyme activity was determined using o-phenylenediamine as a substrate and absorbance was measured on an ELISA reader. Motte et al. teach the characterization of the epitope binding of antibodies in hapten-inhibition experiments. The binding of Mabs to a synthetic peptide linked to a solid-phase support is inhibited by various related amino acids as shown in Table 1. Peptides with sequences in hCT 1-10 and hCT 11-23 did not inhibit Mab CT07 from binding hCT1-32 amide, whereas hCT 24-32 amide, hCT 26-32 amide and hCT 27-32 amide did (page 3334, 3rd paragraph; Table 2 and Figure 2). Motte et al. teach that Mab CT07 only binds to peptides containing a carboxamide group on the proline residue at position 32 of hCT (page 3334, 1st paragraph, second column and Figure 2). Motte et al. teach that Mab CGR01 only binds peptides containing a carboxamide group on the phenylalanine residues at position 37 of hCGRP (page 3334, 2nd paragraph, second column). Motte et al. teach experiments to discern if amino groups located on the side-

chain of amino acids may also modulate antibody binding. Motte et al. teach that Mab QP01 binds to a free amino group borne by the glutamine residue at the N-terminus of PQN-34 peptide.

Claims 1-9, 11, 13, 14, 17-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchison et al. (WO 03/003986 A2).

Hutchison teaches monoclonal or polyclonal antibodies which recognize PTH (page 1 and page 19, lines 22-35). Hutchison teaches that the antibodies will recognize an amino acid sequence from Ser at position 1 to Leu at position 13 of PTH or combinations thereof or in regions consisting of amino acids 14 to 84 or 13 to 34 (page 16). Antibodies are produced by immunizing animals with intact PTH, variants thereof, or mixtures thereof (page 17, lines 15-32 and page 29, lines 11-32). Antibodies are isolated by exposing sera to antibody affinity purification columns. Solid columns are linked with various PTH peptides, including hPTH amino acid residues 1-13, 13-34 and 39-84 (page 18, lines 15-34 and page 30). Hutchison teaches an assay wherein an antibody is immobilized on a solid phase (capture antibody), incubated with an antigen, and further incubated with an antibody with a detectable label (detection antibody) (page 20). Hutchison teaches that antigen can be immobilized on a solid phase incubated with a diluted antiserum or a purified antibody and detectable label, thereby obtaining a labeled binding substance. Hutchison teaches a method wherein an antibody is labeled with a detectable label and the other antibody is allowed to bind to a

solid phase as a solid phase antibody or is made to be able to specifically bind to a solid phase (capture antibody). The antibodies are allowed to react with antigens in various concentrations to form a plurality of antigen-antibody complexes. Since the antigen-antibody complexes are solid phases, the solid phases are separated from the complexes, and the amount of label in the solid phases is measured. The relationship between the label and the concentration of the antigen is plotted to obtain a standard curve (page 21). Hutchison teaches the isolation of antibodies to PTH1-13. Each of the PTH peptides (1-12, 13-34, 38-84) was coupled to sepharose. Goat immune serum was sequentially purified on the affinity columns to first remove anti-PTH38-84 antibodies, then anti-PTH13-34 and then anti-PTH1-13 antibodies (pages 30-31). Hutchison teaches that anti-PTH1-13 antibodies are labeled for detection and anti-PTH39-84 antibodies are labeled for capture. Hutchison teaches that the capture and detection antibodies sandwich the PTH molecules in the sample. The sandwich complex is bound to streptavidin-coated magnetic particles. Hutchison teaches the inhibition of certain PTH peptides (page 33, lines 24-33; page 35, lines 19-29 and page 36, lines 4-19). Hutchison teaches that their results together identify amino acid residues in two distinct regions of PTH (the N-terminus region amino acids 1-2 and 10-13), which are important for antibody binding. Hutchinson et al. state that since these regions are not juxtaposed in the linear sequence of PTH, the bioactive intact N-terminal anti-PTH1-13 antibodies recognize a conformational (non-linear) epitope of PTH (page 36, lines 20-26).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
4/9/07

MARIANNE P. ALLEN
PRIMARY EXAMINER

4/12/07

AU1647